03-SAR-102

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Jordan J. Cohen, M.D., President

February 3, 2003

Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Rd., E-79
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By email: SAPcomments@cdc.gov

Re: Possession, Use, and Transfer of Select Agents and Toxins: Interim Final Rule (67 FR 76886-900)

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the interim final rule regulating the possession, use, and transfer of biological select agents under 42 CFR Part 73.

The AAMC represents all 125 allopathic U.S. medical schools, some 400 teaching hospitals, 94 medical professional societies with approximately 88,000 faculty members, and the nation's 67,000 medical students and 103,000 residents. Our member institutions include leading centers for microbiological and other biomedical research and will play an increasingly important role in strengthening the nation's public health security. Moreover, these institutions and their personnel may find themselves among the responders in the event of a public health emergency. Consequently, the AAMC strongly supports efforts to promote the security and safety of research using select agents.

The AAMC fully endorses the recommendations and comments submitted by the Howard Hughes Medical Institute (HHMI)[1], which were compiled in consultation with environmental and safety officers at leading academic institutions. We urge the Department of Health and Human Services (DHHS) to adopt all of the HHMI proposed revisions, which seek a more consistently performance-based implementation of safety and security procedures in the final rule. We underscore several of these recommendations here for emphasis.

Our chief concern is that the final rule should make explicit the necessary requirements for our institutions to submit and complete successfully a Security Risk Assessment (Section 73.8) from the Department of Justice. Otherwise, we must concur with HHMI that the process outlined in the interim final rule potentially could confound and thwart the DHHS's responsibility to ensure that biological agents and toxins are appropriately available for research, education, and other legitimate purposes as required by the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*. The Department's elucidation of these requirements should rely on extensive input from academic institutions, which are currently subject to various state and other regulations and policies restricting the disclosure of personal information about faculty, staff, and students. The final rule should also provide a process for a subject individual or entity to appeal an adverse security determination.

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[1] Correspondence from W. Emmett Barkley, January 21, 2003, with enclosure, "Comments on 42 CFR Part 73, Interim Final Rule."

The rule's Security provisions (Section 73.11) should be modified to permit institutions to develop or adapt procedures commensurate with the level of risk posed by each agent, which Congress intended, and which would promote a more performance-based strategy for compliance, consistent with the approach engendered by the rule's Safety provisions (Section 73.10).

Again, the AAMC is principally concerned to see that effective security procedures are implemented in a manner that permits continuation of important microbiological, immunological, and related health research. The HHMI's thoughtful and detailed recommendations for revising the security provisions would help ensure this approach.

In other recommendations:

> We are uncertain why Cercopithecine herpesvirus 1 was included in the select agents list (Section 73.4), based on reports of its limited risk of transmission to humans and absence of convincing evidence of spread in aerosols. Macaques, which are the natural host of this virus, are widely used in research and the husbanding and management of this resource—already subject to intensive regulation and guidance—should not be unduly burdened.
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> Under registration requirements (Section 73.7), we recommend deleting the provision (2)(viii) requiring entities to submit, in addition to the specified list of information items, "Any other information necessary for the determination." This language is vague, boundless, and uninformative. The section makes clear elsewhere that the grant of a certificate of registration may be contingent on submission of other *specified* information.
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> We strongly support HHMI's recommendations that DHHS and USDA create a single office for receiving registrations for the possession, use, and transfer of select agents and toxins under their respective regulations (Section 73.7 (c)), to permit a single registration to cover all subject activities on a university campus (Section 73.7(f)), and to validate a certificate of registration for up to five years (Section 73.7(g)).

The AAMC agrees with the Department's observation in the discussion section that many of the rule's provisions codify procedures already developed and set in place by many academic and other institutions conducting research on select agents and toxins. This testifies to the commitment and professional responsibility of academic institutions in accomplishing their research, educational, and public health missions. Recognizing the importance of implementing comprehensive safety and security regulations for select agents and toxins that are workable and effective, and that will not inhibit essential research, the AAMC urges continued and open dialogue between the Federal Government and academic scientists and institutions on these matters.

Sincerely,

Jordan J. Cohen, M.D.